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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,239	10/12/2004	Nadya I Tarasova	229694	1908

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EXAMINER	
KHANNA, HEMANT	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,239	TARASOVA ET AL.	
	Examiner	Art Unit	
	Hemant Khanna	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,49-64,67-71,76-81 and 86-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28, 49-64, 67-71, 76-81, 86-119* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Inventions 1-15, claim(s) 1-28, 49-62, 63-64, 67, 88-98, 99-109, 110-111 drawn to a conjugate comprising ligands with any one of SEQ ID NO: 5-18, and 20

Inventions 16-30, claim(s) 68-69, 78-81, drawn to a method of treating cancer in a mammal comprising administering a conjugate comprising linker FALA and any one of SEQ ID NO: 5-18, and 20

Inventions 31-45, claim(s) 70-71, drawn to a method of delivering a cytotoxic agent administering the conjugate comprising the linker VLALA any one of SEQ ID NO: 5-18, and 20

Inventions 46-60, claim(s) 76-77, drawn to a method of delivering a cytotoxic agent administering the conjugate comprising any one of the linkers ChaLALA, ChaChaLAL, NalChaLaL, or NalLALA with any one of SEQ ID NO: 5-18, and 20

Inventions 61-75, claim(s) 112-113, 116-119 drawn to a method of delivering a cytotoxic agent administering the conjugate comprising the linker ALAL with any one of SEQ ID NO: 5-18, and 20

Inventions 76-90, claim(s) 114-115 drawn to a method of delivering a cytotoxic agent administering the conjugate comprising the linker ALALA with any one of SEQ ID NO: 5-18, and 20

2. The inventions listed as 1-90 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: the sequences of lrepresented by the SEQ ID's disclosed in the independent claims are drawn to ligands that bind to a plethora of receptors with no disclosed common property. Further, the sequences represented by SEQ ID NO: 5-18, and 20 do not share a significant structural element that is essential to one or any common property. Since both the requirements are not met, the sequences of SEQ ID NO: 5-18, and 20 do not meet the requirement of unity of invention (*a priori*). Because these inventions are distinct, the sequences within an inventive group must be restricted further as depicted by the inventions 1-15 for the SEQ ID NO's 5-18, and 20.

3. If any one of inventions 1-90 is elected, the elected invention will be examined only in so far as it pertains to the elected ligand, elected species of that ligand, elected linker and the elected cytotoxic agent.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Linkers with SEQ ID NO's 1-4, 21-24, cytotoxic agents in claims 14, 28, 62, 98, and 109, receptors in claims 4, 18, 52, 88 and 99, and species within the sequences of ligands represented by SEQ ID NO:'s of 9, 13, 15-16.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the unity of invention is lacking *a priori* because the sequences of ligands represented by the SEQ ID NO: 5-18, and 20 do not share a significant structural element or any disclosed common property.

6. Applicant is required, in reply to this action, to elect a single invention 1-90, and elect a completely defined conjugate represented by an elected ligand, linker and cytotoxic agent, compassed within that invention. In inventions 1-90, the species of linkers are independent or distinct because they are drawn to different sequences with different structures. The species of cytotoxic agents are independent or distinct because they are drawn to different chemical structures. Searching all the structures together would impose a serious search burden because the structures are not overlapping variants of each other. Because of the divergent search strategies, searching would be burdensome particularly with regards to the non-patent literature.

7. Further, in inventions 1-90, the receptors are drawn to proteins that are activated by non-overlapping agonists (ligands) having diverse biological responses. Searching all the receptors together would impose a serious search burden because their sequences are not overlapping variants of each other.

8. Applicant is advised that a reply to this requirement must include (i) an identification of the SEQ ID NO: of linker, species of cytotoxic agent, species of receptor, and any species within an elected invention of a particular ligand SEQ ID NO. that is elected consonant with this requirement, and (ii) a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence not of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Hemant Khanna Ph.D.
January 6, 2007